SK

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,358	08/25/2003	Charles Larry Bisgaier	5790-C1	2219

7590 07/01/2004

Heidi M. Berven
Warner-Lambert Company, LLC
2800 Plymouth Road
Ann Arbor, MI 48105

EXAMINER	
WEBMAN, EDWARD J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

10/647358

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
	6/1/04

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/19/03.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-28 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11/24/03
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-421-632/40206

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, 12-13, 15-16, 19-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Glueck et al.

Glueck et al. teach the combination of gemfibrozil and lovastatin (see Glueck et al., page 1, right column, lines 5-6, and line 14).

Gemfibrozil was known to the art as an Lp(a) inhibitor before applicants' filing date (Ramharack et al., page 48, abstract, right column, lines 9-10.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bocan, US Patent No. 6,093,719 in view of Lee et al.

Bocan teaches lowering LDL levels and an HMG-CoA-reductase inhibitor to treat coronary artery disease. Atorvastatin is disclosed (abstract; column 1, lines 47 to 54; and column 2, lines 40 to 44).

Bocan does not teach lowering Lp(a) levels.

Lee et al teaches 9-cis-retinoic acid to lower Lp(a), and that Lp(a) is a modified form of LDL and is implicated in coronary heart disease (abstract; column 1, lines 36 to 46, and claim 60.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to further enhance the treatment of coronary artery disease in Bocan by adding 9-cis-retinoic acid in view of Lee et al.

As to the claimed kit, such packaging is well known in the pharmaceutical art.

See In re Kerkhoven 205 USPQ 1069. The combination of agents, each of which is known to be useful individually for the same purpose, into a single composition useful for the very same purpose, e.g. *treating coronary disease*, is prima facie obvious. At least additive therapeutic effects would be reasonably expected.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai et al. (US Patent No. 5,260,440) in view of Katocs, Jr. et al. (US Patent No. 5,219,888).

Hirai et al. Teach HMG CoA reductase inhibitors are useful in treatment of atherosclerosis (see abstract). Pravastatin is specified (see column 1, lines 9-12).

Hirai et al. Do not teach 9-cis-retinoic acid.

Katocs, Jr. et al. Teach 9-cis-retinoic acid is useful in protecting against premature atherosclerosis (see column 2, lines 25, 48-51).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add 9-cis-retinoic acid to the composition of Hirai et al.

to further achieve additional effectiveness of treating atherosclerosis in view of Katocs, Jr. et al.

See In re Kerkhoven 205 USPQ 1069. The combination of agents, each of which is known to be useful individually for the same purpose, into a single composition useful for the very same purpose, e.g. *treatment of atherosclerosis*, is prima facie obvious. At least additive therapeutic effects would be reasonably expected.

As to the claimed kit, such packaging is well known in the pharmaceutical art.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites Atorvastatin, contradicting claim 6.

No claims allowed.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

Webman/tgd

June 2, 2004